Applicants: Jansen et al. Application No.: 10/717.058

Filing Date: November 19, 2006

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## REMARKS

Reconsideration of the application is respectfully requested.

Claims 1-15 and 21-35 are in the application. Through this Amendment, claims 1, 12, 21 and 31 have been amended.

In the Official Action, the Examiner rejected claims 1-15 and 21-35 under 35 U.S.C. §103(a) as being allegedly unpatentable over Bitdinger et al. (U.S. Patent No. 5,478,316).

Bitdinger et al. is directed to an automatic self-injection device. The device includes a sleeve 28 formed to enclose needle 38. Fig. 3 shows the device prior to use with the sleeve 28 covering the needle 38. (See, col. 3, II. 33-44). With reference to Fig. 5, the sleeve 28 covers the needle 38 prior to use, with the sleeve 28 being pressed against a patient's skin to perform use. (See, col. 5, II. 51-59). As shown in Figs. 6-8, after use, the sleeve 28 is driven back to a shielding position, as shown in Fig. 8. (See, col. 6, II. 22-28).

Claims 1, 12, 21 and 31 are the pending independent claims of the application. Each of these independent claims includes the limitation that the "shield is initially in said retracted position". Bitdinger et al. does not provide this arrangement. Rather, in Bitdinger et al., the shield is initially in an extended position, <u>not</u> a retracted position. With the subject invention, a needle shield arrangement is provided which allows for a needle tip to be initially exposed to facilitate use by a practitioner in, e.g., priming a needle and inserting the needle into a patient.

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Bitdinger et al. does not allow for such exposure. It is respectfully submitted that claims 1, 12, 21 and 31, along with dependent claims 2-11, 13-15, 22-30 and 32-35, are patentable over Bitdinger et al.

The Examiner rejected claims 1, 12, 21 and 31 under 35 U.S.C. §112, second paragraph, as being allegedly incomplete for omitting central structural cooperative relationships of elements. The Examiner specifically indicated that he is "not able to see where the spring directly biases the shield (59) with the holder (40)."

In response, claims 1, 12 and 31 have been amended to indicate that the spring is "for urging said shield towards said extended position". Claim 21 has been amended to indicate that a spring is provided which is "partially compressed within said holder so as to bias said shield towards said extended position". It is respectfully submitted that the claims as amended are fully supported by the specification and are in accord with 35 U.S.C. §112.

In the Official Action, the Examiner objected to the drawings for allegedly failing to include the limitation of the "spring operably biased between said holder and said shield". As indicated above, this limitation has been deleted from the claims. It is respectfully submitted that the objection to the drawings has been overcome.

The Examiner also provisionally rejected claims 1-15 and 21-35 on the ground of nonstatutory obviousness-type double patenting as being allegedly unpatentable over claims 1-10 of Applicants: Jansen et al. Application No.: 10/717,058 Filing Date: November 19, 2006

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co-pending Application No. 10/737,627. In response, attached hereto is a terminal disclaimer. It is respectfully submitted that the double patenting rejection has been overcome with the filing of this terminal disclaimer.

Favorable action is earnestly solicited. If there are any questions or if additional information is required, the Examiner is respectfully requested to contact Applicants' attorney at the number listed below.

Respectfully submitted,

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